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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/614,599	07/07/2003	David P. Andrew	09800080-0104	7759	
23552 MERCHANT &	7590 10/29/2007 & GOULD PC	EXAMINER			
P.O. BOX 2903	3	DEBERRY, REGINA M			
MINNEAPOLI	S, MN 55402-0903)903	ART UNIT	PAPER NUMBER	
	•		1647		
			MAIL DATE	DELIVERY MODE	
•			10/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
	10/614,599	ANDREW ET AL.					
Office Action Summary	Examiner	Art Unit					
	Regina M. DeBerry	1647					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONEI	I. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
 1) Responsive to communication(s) filed on 27 August 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 							
Disposition of Claims							
 4) Claim(s) 19,38,42-48,51-57,61-64 and 66-75 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 19,38,42-48,51-57,61-64 and 66-75 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 							
Application Papers		,					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
Attach we and (a)							
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/07.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	ite					

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 August 2007 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 27 August 2007 has been entered in full. Claims 1-18, 20-37, 39-41, 49, 50, 58-60, 65 are canceled. Claims 19, 38, 42-48, 51-57, 61-64, 66-75 are pending and under examination.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 27 August 2007 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Withdrawn Objections And/Or Rejections

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The rejection to claims 19, 38, 42-60 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 8-10 of the previous Office Action (02 February 2007), is *withdrawn* in view of the amendment (27 August 2007).

The objection to claims 19, 38 and 59, as set forth at page 10 of the previous Office Action (02 February 2007), is *withdrawn* in view of the amendment (27 August 2007).

The rejection to claims 19, 42-50 under 35 U.S.C. 112, second paragraph, as set forth at page 10 of the previous Office Action (02 February 2007), is *withdrawn* in view of the amendment (27 August 2007).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 38, 42-48, 51-57, 61-64, 66-75 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis for this rejection is set forth at pages 3-8 of the previous Office Action (02 February 2007).

Applicant states that the Office Action alleges the tumor marker data provided in the specification does not enable the full scope of the claims. Applicant states that the Examiner alleges it is unclear if the nucleic acid levels are enhanced or decreased compared to normal control tissues because of inconsistent expression of the nucleic acid molecules in the same tissues and concludes it is not clear which samples are

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statistically significant. Applicant submits that the Examiner is requiring Applicants to establish enablement to a higher degree of certainty than is required. An enabling disclosure only requires a reasonable correlation to the scope of the claims and that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied (In re Fischer, 427 F.2d 833, 839(CCPA 1970)). For a claimed genus, representative examples coupled with a statement applicable to the genus as a whole are ordinarily sufficient to comply with the enablement requirement (MPEP § 2164.02). Applicant argues that the claims have been amended to recite detecting an alteration in expression of the nucleic acid molecules in a tumor cell compared to a normal cell. Applicant argues that Table 8 shows expression of the nucleic acid molecules is altered in pancreas, liver, colon, stomach, thyroid, kidney, and bladder cancer cells relative to normal cells from the respective tissues. Table 9 shows expression of the nucleic acid molecules in tumor tissue compared to normal adjacent tissue in the same patient or normal tissue from a different patient. Applicant argues that in some instances, expression of the nucleic acid molecules is increased relative to the control (see, for example, colon and liver in Tables 8 and 9) and that in some instances, expression of the nucleic acid molecules is decreased relative to the control (see, for example, kidney and prostate). Applicant maintains that an increase or decrease in expression of the nucleic acid molecules in tumor cells or tumor tissue relative to the control cells or control tissue was indicative of cancer. Applicant submits the data provide in Tables 8 and 9 provide a reasonable

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correlation between an alteration in expression of the nucleic acid molecules in the recited cells and tissues and cancer. Applicant states that contrary to the Examiner's assertion, Tables 8 and 9 provide a control cell or control tissue for each cell type or tissue type and that post filing date information, indicates that the polypeptide comprising SEQ ID NO:6 has been categorized as S100 protein A14. Applicant submits an alignment. Applicant states that members of the S100 family have been implicated as markers for cancer tissue. Applicant state that with respect to the results presented in the application for breast, prostate, and colon cancer, analysis of circulating tumor cells indicates that S100A14 serves as a marker for breast cancer and colon cancer cells. Applicant cites Smirnov et al. (Cancer Res.65:4993, 2006).

Applicant's arguments have been fully considered but are not deemed persuasive. The instant claims remain rejected because the specification was not enabling as of the filing date (18 November 1999; filing date of the instant application). That is to say that the specification failed to teach how to use the instant invention of determining cancer of the pancreas, liver, colon, thyroid, kidney or bladder at the time of filing. The Examiner has cited some of the teachings from MPEP 2164.05 (a) [R-2]. "The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the

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time of filing. In re Gunn, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); In re Budnick, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, Applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. Gould v. Quigg, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987)".

Applicant argues that the claims have been amended to recite detecting an alteration in expression of the nucleic acid molecules in a tumor cell compared to a normal cell. This argument is not found persuasive. If one skilled in the art had a sample of normal tissue and possible cancerous tissue, what type of alteration would the skilled artisan be looking for? Does alteration mean overexpression or underexpression? It is unclear how the limitation "altered" enables one skilled in the art to discern cancer in a particular type of tissue. Botsein et al., US Patent 7,157,247 B2, for example, teach a gene that is amplified in certain cancer or cancer cell lines (column 547-561). The skilled artisan would know to look for an overexpression of the gene of Botsein et al. in cancer samples. Applicant cites Smirnov et al. (Cancer Res.65:4993, 2006) and argues that with respect to the results presented in the application for breast, prostate, and colon cancer, analysis of circulating tumor cells indicates that S100A14 serves as a marker for breast cancer and colon cancer cells. The Examiner does not doubt that S100A14 can serve as a marker for certain cancers based on Smirnov et al. But, publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing.

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Applicant argues that in some instances, expression of the nucleic acid molecules is increased relative to the control (for example, colon and liver in Tables 8 and 9) and that in some instances, expression of the nucleic acid molecules is decreased relative to the control (for example, kidney and prostate). This argument is not found persuasive. The specification teaches the quantitative expression of SEQ ID NO:5 in various tissue. The specification teaches normal kidney tissue with an SEQ ID NO:5 expression level of 4.6 and renal carcinomas with numbers of 0.1 (Table 8). Normal kidney tissue from surgical tissue had a SEQ ID NO:5 expression number of 2.9, surgical kidney cancers had numbers of 2.4 (Table 9, page 91). However, the specification states that the results in Table 8 indicate that the clone of SEQ ID NO:5 is very strongly expressed in several tumor derived cell lines compared with normal tissue (see page 88, lines 1-10 and page 91, lines 1-8). This is an example of an inconsistency because the gene appears to be underexpressed in kidney, but the summary of the data teaches that SEQ ID NO:5 is strongly expressed. It is unclear how one skilled in the art can use this particular teaching. The specification teaches normal colorectal tissue with a SEQ ID NO:5 expression level of 3.6 (page 87) and colon carcinomas with levels of 0.3, 4.3, 12.0, 31.4, 44.2 and 100 (page 88). Surgical normal colon tissue had a SEQ ID NO:5 expression level of 22.4, CC Well to Mod Diff had a level of 32, CC NAT had a level of 11.5, CC NAT had a level of 2.7, CC Mod Diff had a level of 5.7, CC NAT had a level of 5.2, CC NAT had a level of 10.8 (page 90). This is another example of an inconsistency because it is not clear if this gene is overexpressed or underexpressed in colon cancer compared to normal colon tissue. The Examiner suggested in a phone interview (27

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August 2007) that Applicant provide teachings (e.g. literature, declarations, etc.), which would explain the inconsistencies in the data and why the data is still statistically relevant. The literature and arguments submitted by Applicant fail to address the instant issues. Applicant maintains that an increase or decrease in expression of the nucleic acid molecules in tumor cells or tumor tissue relative to the control cells or control tissue is indicative of cancer. However, this is not necessarily clear from the instant data and the instant claims fail to recite such limitations.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

NEW CLAIM REJECTIONS/OBJECTIONS

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 42-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "detecting an amount of said nucleic acid molecule in said sample,

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wherein a <u>change in expression</u> as compared to normal cells of the same tissue type is indicative of cancer". Applicant's amendment, filed 27 August 2007, states that the claims have been amended to further clarify the claimed invention.

The Examiner cannot locate support for the deletion of "enhanced" in the limitation, "...wherein a change in enhanced expression of the nucleic acid molecule..". The wording or connotation of the instant claim(s) is not readily apparent and Applicant does not provide sufficient direction for the written description for the above-mentioned "limitations".

Furthermore, the specification teaches that, "the results in Table 8 indicate that the clone of SEQ ID NO:5 is very strongly expressed in several tumor derived cell lines compare with normal tissue, especially colon tumor cells, breast tumor cells and ovarian tumor cells" (page 88, lines 4-7). The specification also states, "the results shown in Table 9 demonstrate that 65677221-3 frag is strongly upregulated by cancer cell lines and tumor, compared to normal and normal adjacent tissue". "This is especially true for cancers of the breast, ovary, colon, stomach and pancreas" (page 91, lines 2-6).

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Art of Record

The art made of record and not relied upon is considered pertinent to Applicant's disclosure are WO document, WO 99/47669 and foreign document, DE 198 13 839 A1. The instant references teach the polynucleotide sequence which is 100% identical to a polynucleotide sequence encoding instant SEQ ID NO:6. See Appendix A, result #7 and Appendix B, result #6. The instant documents identify their sequence as encoding a calcium binding protein. However the instant references teach that their nucleic acid sequence can be used to identify breast cancer and thus cannot be considered prior art because the instant claims recite a method for detecting cancer using a nucleic acid encoding the amino acid of SEQ ID NO:6 in pancreas, liver, colon, thyroid, kidney or bladder cancer cells.

The art made of record and not relied upon is considered pertinent to Applicant's disclosure is Pietas et al. (Molecular cloning and characterization of the human S100A14 gene encoding a novel member of the S100 family; Genomics, Vol. 79, No. 4, April 2002). The instant references teach the polynucleotide sequence which is 100% identical to a polynucleotide sequence encoding instant SEQ ID NO:6. See Appendix B, result #4. Pietas et al. teach the heterogenic expression of S100A14 in tumors, demonstrating its overexpression in breast and underexpression in kidney. However the instant reference has a publication date of April 2002 and thus cannot be considered prior art.

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Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Regina M. DeBerry whose telephone number is (571)

272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

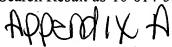
USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/23/07

Marianne P. allen
MAHIANNE P. ALLEN
PRIMARY EXAMINER

AU 1647 10/26/07



SCORE Search Results Details for Application 10614599 and Search Result us-10-614-599-6.p2n.rng.

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SCORE System Overview SCORE FAO Comments / Suggestions

This page gives you Search Results detail for the Application 10614599 and Search Result us-10-614-599-6.p2n.rng.

Go Back to previous page

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GenCore version 5.1.9
                     Copyright (c) 1993 - 2006 Biocceleration Ltd.
OM protein - nucleic search, using frame plus p2n model
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                                                    (without alignments)
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                   US-10-614-599-6
Perfect score:
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       Pred. No. is the number of results predicted by chance to have a
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       and is derived by analysis of the total score distribution.
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SUMMARIES

Moberatix	A
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Res	ult		Query				
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	2	614	100.0	1026	14	AED26049	Aed26049 Novel hum
	3	614	100.0	1057	8	ACC50213	Acc50213 Breast ca
	4	614	100.0	1057	12	ADN04843	Adn04843 Antipsori
	5	614	100.0	1057	13	ADX97504	Adx97504 Pancreati
	6	614	100.0	1057	14	AEB35221	Aeb35221 Human Gef
	7	614	100.0	1105	2	AAZ33627	Aaz33627 Human bre
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ALIGNMENTS

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DR
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     designated (FCTRX) and the nucleic acid that encodes it, useful for
PT
XX
     preventing, diagnosing and treating e.g. cancers and inflammation.
```

Appendix A

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614.00
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Qу
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хx
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XX
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    (META-) METAGEN GES GENOMFORSCHUNG MRH.
ХX
    Specht T, Hinzmann B, Schmitt A, Pilarsky C, Dahl E, Rosentahl A;
хx
DR
    WPI; 1999-528981/45.
XX
PT
    Human nucleic acid sequences and protein products from tumor breast
    tissue, useful for breast cancer therapy.
XX
PS
    Claim 1a; 97; 188pp; German.
XX
CC
    This invention decribes novel human nucleic acid sequences from tumor
    breast tissue which have cytostatic activity. The nucleic acid sequences can be used to produce and isolate full-length gene sequences. They can
CC
    be used to express proteins, which can be used as tools to find an
CC
    activity against breast cancer. The sequences can be used in sense or
CC
    antisense form. They are especially useful for medicaments for gene
CC
    therapy to treat breast cancer. AAZ33611-Z48617 represents expressed
    sequence tags described in the method of the invention
ХX
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PΙ
               Bangur CS, Lodes MJ, Fanger GR, Vedvick TS, Carter D;
PΙ
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DR
     WPI; 2001-071488/08.
PT
     Lung tumor-associated proteins and the nucleic acids that encode them,
PT
     useful for preventing, diagnosing and treating lung cancer.
ХX
     Claim 4; Page 174; 436pp; English.
CC
     The present invention describes immunogenic portions of lung tumour-
CC
     associated proteins (I) and the nucleic acids (NAs) that encode them. (I)
     have cytostatic activity and can be used in gene therapy, antisense
     inhibition and in vaccines. The NAs and the lung tumour-associated
     proteins they encode may be used in the prevention, treatment and
     diagnosis of diseases associated with their inappropriate expression,
CC
     especially lung cancers. For example, the NAs may be administered to
     treat diseases by rectifying mutations or deletions in a patient's genome
     that affect the activity of the protein by expressing inactive proteins or to supplement the patients own production of (I). Additionally, the
     NAs may be used to produce the lung-tumour associated protein, according
     to standard recombinant DNA methodology. Conversely, antisense NA
CC
     molecules may be administered to down regulate protein expression by
     binding with the cells own genes and preventing their expression. The NA and complementary sequences may also be used as DNA probes in diagnostic assays to detect and quantitate the presence of similar NA sequences in
CC
     samples, and hence which patients may be in need of treatment for lung cancer. The (I) may be used as antigens in the production of antibodies and in assays to identify modulators (agonists and antagonists) of the
CC
     expression and activity of the protein. AAF68083 to AAF68878 and AAB76848
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     to AAB76878 represent human lung tumour protein related nucleotide and protein sequences which are used in the exemplification of the present
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CC
     invention
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Alignment Scores:

http://es/ScoreAccessWeb/GetItem.action?AppId=10614599&seqId=09323b6780071198... 10/23/2007



Score Home Page Retrieve Application List SCORE System Overview SCORE FAQ Comments / Suggestions

This page gives you Search Results detail for the Application 10614599 and Search Result us-10-614-599-6.p2n.rge.

Go Back to previous page

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GenCore version 5.1.9
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SUMMARIES

Appendix	3
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      cognitive disorder; psoriasis; clone 7971c.7; expressed sequence tag;
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PA
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      Rastelli L, Lewin D, Taillon B, Andrew DP;
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      WPI; 2001-329224/34.
DR
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      {\tt S100} cytokine-like polypeptide member of the Wnt signaling pathway designated (FCTRX) and the nucleic acid that encodes it, useful for
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      preventing, diagnosing and treating e.g. cancers and inflammation.
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appendix B
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 AUTHORS
           Rosenthal, A.D., Pilarsky, C., Dahl, E., Specht, T., Bruemmendorf, T.,
           Lichtner, R., Staub, E., Roepcke, S. and Li, X.I.
  TITLE
           Human nucleic acid sequences expressed in pancreatic carcinomas
           Patent: EP 1471075-A 52 27-OCT-2004;
  JOURNAL
            Hinzmann, Bernd (DE); Rosenthal, Andre (DE); Pilarsky, Christian
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           Pietas, A., Petersen, I., Schluens, K. and Petersen, S
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  JOURNAL
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  TITLE
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  JOURNAL
           Submitted (17-AUG-2000) Institute of Pathology, Charite Hospital,
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Appendix B

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               DUHL EDGAR
           ΡI
               ANDRE ROSENTHAL
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          Schmitt, A., Specht, T., Dahl, E., Hinzmann, B., Rosenthal, A. and
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          Human nucleic acid sequences from tissue of breast tumors
          Patent: WO 9947669-A 17 23-SEP-1999;
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US-10-614-599-6 (1-118) x AX017266 (1-1105)
Qу
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Db
        138 GACAACAGAACTCTCACCAAAGGACCAGACACAGTGAGCACCATGGGACAGTGTCGGTCA 197
        Qν
Db
        Qy
Db
           Db
           CGGGACCTGGTCACCCAGCAGCTGCCCCATCTCATGCCGAGCAACTGTGGCCTGGAAGAG 377
Qy
        Db
Qу
        101 LeuIleGlyGluAlaAlaLysSerValLysLeuGluArgProValArgGlyHis 118
           Db
        438 CTGATTGGAGAAGCGGCCAAGAGTGTGAAGCTGGAGAGGCCTGTCCGGGGGCAC 491
RESULT 7
AX524970
LOCUS
          AX524970
                             1105 bp
DEFINITION
         Sequence 17 from Patent EP1236799.
ACCESSION
         AX524970
VERSION
         AX524970.1 GI:25170052
SOURCE
         Homo sapiens (human)
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